Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Monitoring modalities and assessment of fluid status: a practice management guideline from the Eastern Association for the Surgery of Trauma.

Bibliographic Source(s)

Plurad DS, Chiu W, Raja AS, Galvagno SM, Khan U, Kim DY, Tisherman SA, Ward J, Hamill ME, Bennett V, Williams B, Robinson B. Monitoring modalities and assessment of fluid status: A practice management guideline from the Eastern Association for the Surgery of Trauma. J Trauma Acute Care Surg. 2018 Jan;84(1):37-49. [74 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

= Poor = Fair = Good = Very Good = Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source
	Disclosure and Management of Financial Conflict of Interests
	Guideline Development Group Composition
YES	Multidisciplinary Group

UNKNOWN	Methodologist Involvement
▮▯▯▯▯	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
▮▮▮▮▯	Search Strategy
▮▮▮▮▮	Study Selection
▮▮▮▮▮	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
▮▮▮▮▮	Grading the Quality or Strength of Evidence
▮▮▮▮▮	Benefits and Harms of Recommendations
▮▮▮▮▮	Evidence Summary Supporting Recommendations
▮▮▮▮▮	Rating the Strength of Recommendations
▮▮▮▮▮	Specific and Unambiguous Articulation of Recommendations
▮▮▯▯▯	External Review
▮▯▯▯▯	Updating

Recommendations

Major Recommendations

The strength of recommendation (strong or weak/conditional) and levels of evidence (high, moderate, low or very low) are defined at the end of the "Major Recommendations" field.

Results for the Use of Focused Ultrasound for Fluid Responsiveness (Population, Intervention, Comparator, and Outcome [PICO] 1)

In surgical patients being evaluated for shock (P), should a protocol that includes focused ultrasound (I) be utilized versus a standard protocol (C) to predict fluid responsiveness (O)?

Grading the Evidence PICO Question 1

As per QUADAS-2, risk of bias and applicability concerns were generally "unclear" to "high," and therefore the overall quality of the evidence as it pertains to PICO 1 is considered low.

Recommendations for the Use of Focused Ultrasound for Fluid Responsiveness (PICO 1)

The Panel conditionally recommends the use of focused ultrasound to determine fluid responsiveness in the management of a mixed population of surgical patients being evaluated for shock. There is a lack of clear superiority of focused ultrasound for this outcome. Focused ultrasound is only useful for the clinician with the training and maintenance of the skill to correctly perform the examination and demonstrates an understanding of the populations of patients that are appropriate for this modality.

Results for the Use of Focused Ultrasound to Reduce Complications and Organ Failures and Complications (PICO 2)

In surgical patients being resuscitated from shock (P), should a protocol that includes focused ultrasound (I) be utilized versus a standard protocol (C) to reduce organ failures or complications (O)?

Grading the Evidence PICO Question 2

There was serious risk of bias in this one qualifying study for the use of historical controls and for the ill-defined "eye ball" protocol. Additionally, since the number of surgical patients was not reported, there were indirectness concerns. Although the magnitude of effect appears significant, one could not upgrade this single study. The overall quality of the evidence for PICO 2 is very low.

Recommendations for the Use of Focused Ultrasound to Reduce Organ Failures and Complications (PICO 2)

The Panel conditionally recommends the use of focused ultrasound to decrease organ failures and complications in surgical patients being treated for shock. This is based on a lack of high-quality studies that assess organ failures, whereas the single included study had serious methodological concerns. Dependence on focused ultrasound for the purposes of reductions in complications and organ failure should be discouraged outside of an overall protocol.

Results for the Use of Focused Ultrasound to Reduce Mortality (PICO 3)

In surgical patients being resuscitated from shock (P), should a protocol that includes focused ultrasound (I) be utilized versus a standard protocol (C) to reduce mortality (O)?

Grading the Evidence PICO Question 3

Risk of bias was serious. Only one study randomized with a computer-generated sequence while others assigned by day of admission or used historical controls. Only one study relates to the population of interest, and one other study did not address the comparison of interest. Therefore, quality was assessed as very low.

Recommendations for the Use of Focused Ultrasound to Reduce Mortality (PICO 3)

The Panel conditionally recommends the use of focused ultrasound to reduce mortality in surgical patients in shock. This is based on the very low quality of studies related to this outcome. Further, focused ultrasound is only one contributor in an overall protocol designed to improve outcomes; however, protocols were not clearly articulated.

Results for the Use of Arterial Pulse Waveform Analysis (APWA) to Predict Fluid Responsiveness (PICO 4)

In surgical patients being evaluated for shock (P), should a protocol that includes APWA (I) be utilized versus a standard protocol (C) to predict fluid responsiveness (O)?

Grading the Evidence PICO Question 4

The quality of evidence domains using QUADAS-2 was generally "low" to "unclear." Further, there was high risk of selection bias in two studies where patients were identified on subjective measures for varied indications. Applicability concerns were high risk in four (67%) studies. Additionally, unknown confounding is introduced when the same technology is used as the index test and to define the reference standard.

Recommendation for the Use of APWA to Predict Fluid Responsiveness (PICO 4)

The Panel conditionally recommends the use of APWA to predict fluid responsiveness in surgical patients being evaluated for shock. This is based on the concern for applicability and, thus, low quality of the evidence. Similarly, APWA devices should only be used by the clinician who understands its indications and limitations.

Results for the Use of APWA for Reducing Organ Failure and Complications (PICO 5)

In surgical patients being resuscitated from shock (P), should a protocol that includes APWA (I) be utilized versus a standard protocol (C) to reduce organ failures or complications (O)?

Grading the Evidence PICO Question 5

The quality of the evidence was assessed as "low" for this outcome. Results varied across patient populations and the device used, thus indirectness was a significant concern. Studies were small and confidence intervals were wide.

Recommendation for Use of APWA for Reducing Complications and Organ Failures (PICO 5)

The Panel conditionally recommends the use of APWA to decrease complications or organ failures in surgical patients being treated for shock. This is based on the widely varied results across different populations. Although APWA is favored in select patients yielding meta-analysis results that appear favorable, this should be approached with caution given a low number of high-quality studies. However, patients and clinicians may prefer a less-invasive option with a strong understanding of the limitations.

Results for the Use of APWA Devices to Reduce Mortality (PICO 6)

In surgical patients being resuscitated from shock (P), should a protocol that includes APWA (I) be utilized versus a standard protocol (C) to reduce mortality (O)?

Grading the Evidence PICO Question 6

Overall grade of the evidence was low. There was concern for indirectness since 50% of studies were conducted intraoperatively or were in the setting of medical critical illness or a low percentage of surgical patients.

Recommendation for the Use of APWA Devices to Decrease Mortality (PICO 6)

The Panel conditionally recommends the use of APWA to reduce mortality. This is based on results that essentially show equivalence to comparators. Any use of APWA mandates a thorough understanding of the narrow clinical application profile supported by published data.

Definitions

Grading of Recommendations Assessment, Development and Evaluation (GRADE) Methodology Levels for Rating the Quality of Evidence

Quality Level	Definitions
High	Very confident that the true effect lies close to estimate of effect.
Moderate	Moderate effect; true effect is likely close to estimate of effect but may be substantially different.
Low	Limited confidence; true effect may be substantially different from estimate of effect.
Very Low	Little confidence; true effect likely substantially different from estimate of effect.

GRADE Definition of Strong and Weak Recommendation

	Strong Recommendation	Weak/Conditional Recommendation
For patients	Most patients would want the recommended course of action.	Most patients would want the recommended course of action, but many would not.
For clinicians	Most patients should receive the recommended course of action.	Different choices will exist for different patients, and clinicians should help patients decide.
For policy makers	Recommended course should be adopted as policy.	Considerable debate and stakeholder involvement needed to make policy.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Shock

Guideline Category

Assessment of Therapeutic Effectiveness

Evaluation

Management

Treatment

Clinical Specialty

Critical Care

Emergency Medicine

Surgery

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To define the role of focused ultrasound and arterial pulse waveform analysis (APWA) for surgical patients in shock

Target Population

Adult surgical patients being evaluated for shock

Interventions and Practices Considered

1. Focused ultrasound
2. Arterial pulse waveform analysis (APWA)

Major Outcomes Considered

- Mortality
- Fluid responsiveness
- Organ failure or complications

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Inclusion and Exclusion Criteria

Study Types

The Panel included prospective randomized trials, case control studies, prospective observational studies, retrospective observational trials, and cohort studies with comparator groups.

Participant and Setting Types (Population, P)

The Panel included adult surgical patients being evaluated for shock. This included hemodynamic instability or other indications for which fluid administration was considered. The Panel also included studies of nonsurgical populations if the predominant diagnosis was severe sepsis, but downgraded the evidence for indirectness. The Panel restricted the settings to the emergency department (ED), the intensive care unit (ICU) and the operating room. However, since resuscitation from shock should be rare in the elective operative setting, the Panel downgraded the level of evidence in these studies.

Intervention Type(s) (I)

The Panel included studies addressing the use of focused ultrasound or arterial pulse waveform analysis (APWA) for resuscitative guidance. The Panel excluded studies addressing focused assessment with sonography for trauma or pulse pressure variation (PPV) as it considered these discrete modalities.

Comparison Type(s) (C)

Studies comparing focused ultrasound or APWA to static variables (central venous pressure [CVP], pulmonary artery occlusion pressure [PAOP], vital signs) were included in quantitative analysis. The Panel included studies where the comparator was "standard management" but downgraded for bias concerns since protocols were inconsistently defined. The Panel included studies where the comparator was PPV. The Panel excluded comparisons of focused ultrasound to APWA.

Outcome Measure Types (O)

In accordance with Grading of Recommendations Assessment, Development and Evaluation (GRADE), critical outcomes of mortality, fluid responsiveness and organ failure were selected by the working group. Fluid responsiveness was assessed by cardiac output (CO), stroke volume or any determinant, such as velocity time integrals (VTI). The Panel analyzed organ failures and complications in aggregate since there were a low number of studies that addressed organ failures alone. The Panel then downgraded the evidence for this surrogate outcome.

Methods

Search Strategy

Two searches of PubMed, MEDLINE and the Cochrane Register of Controlled Trials for articles published from January 1, 1992, to December 31, 2016, were performed. The focused ultrasound search included the terms: *Bedside Ultrasound, Hemodynamic Ultrasound, focused ultrasound, Point of Care Ultrasound, ICU ultrasound, Limited Ultrasound, Fluid responsiveness, Resuscitation*, and *Echocardiography*. The APWA search included the terms: *Arterial waveform analysis, Stroke Volume Variation, Systolic Pressure Variation, noninvasive monitoring, Arterial Pressure Waveform Analysis, Pulse Power Analysis, Pulse Contour Analysis, Transpulmonary Thermodilution, LiDCO, PiCCO, FloTrac*, and *fluid responsiveness*. The "related articles" function and manual review of bibliographies were used to broaden the search.

Study Selection

A team member accessed all abstracts and assessed general relevance to the review. A second team member reviewed the determinations. A third team member was available for disagreements. Reviews, case reports, technical papers, letters to the editor, and non-English language publications were excluded. Abstracts were distributed among team members and full text articles were accessed if considered appropriate.

Number of Source Documents

Search Results: Focused Ultrasound

A total of 151 abstracts were identified (see Figure 1A in the original guideline document). After eliminating duplicates, 135 were screened. After exclusions, 47 full text articles were reviewed with 12 studies meeting inclusion criteria.

Search Results: Arterial Pulse Waveform Analysis

A total of 108 abstracts were identified (see Figure 1B in the original guideline document). After eliminating duplicates, 98 were screened. After exclusions, 60 full text articles were reviewed with 20 studies meeting inclusion criteria.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Grading of Recommendations Assessment, Development and Evaluation (GRADE) Methodology Levels for Rating the Quality of Evidence

Quality Level	Definitions
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Very Low	Little confidence; true effect likely substantially different from estimate of effect.

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Data Extraction and Management

Data including methodology, population, and outcome, was entered into Review Manager (RevMan) (Version 5.3: Cochrane Collaboration, Oxford). Forest plots were generated when appropriate. The data for fluid responsiveness were used to generate evidence tables.

Assessment of Methodological Quality

Data were entered into GRADEpro (Version 3.2, Cochrane Collaboration, Oxford) to generate quality of evidence tables. However, since the quality of studies evaluating diagnostic test (DTA) accuracy differ, the QUADAS-2 tool was implemented in RevMan to assess methodological quality for fluid responsiveness studies. QUADAS-2 addresses bias and applicability concerns as "low," "unclear," or "high" across relevant domains.

Data Synthesis and Statistical Analysis

The Panel performed a meta-analysis where adequate data were reported to calculate incidence of outcomes for comparison. In accordance with recommendations of Cochrane reviews of diagnostic test accuracy (DTA), pooled sensitivities were not calculated.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Recommendations

The Panel considered the risk-benefit of using the modalities and potential patient and clinician preferences. The Panel prefaced strong recommendations with "The Panel recommends," and weak recommendations with "The Panel conditionally recommends."

Rating Scheme for the Strength of the Recommendations

Grading of Recommendations Assessment, Development and Evaluation (GRADE) Definition of Strong and Weak Recommendation

	Strong Recommendation	Weak/Conditional Recommendation
For patients	Most patients would want the recommended course of action.	Most patients would want the recommended course of action, but many would not.
For clinicians	Most patients should receive the recommended course of action.	Different choices will exist for different patients, and clinicians should help patients decide.
For policy makers	Recommended course should be adopted as policy.	Considerable debate and stakeholder involvement needed to make policy.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Not stated

Description of Method of Guideline Validation

Not applicable

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

With training in identification of appropriate subpopulations, procedural details and interpretation of data, focused ultrasound or arterial pulse waveform analysis (APWA) can be associated with favorable outcomes when compared with traditional management.

Potential Harms

- The risk of faulty interpretation of the focused ultrasound findings can be high and can lead to medicolegal consequence. Focused ultrasound has a narrow application profile, having been shown to be inaccurate in the setting of arrhythmias, other cardiac dysfunction, early hemorrhage, and spontaneous breathing. Despite these limitations, the Panel would presume that some patients and clinicians may prefer a noninvasive means of monitoring. However, an absolute requirement for the use of focused ultrasound is the appropriate training and maintenance of skill needed to perform the examination, interpret the results and understanding of the limitation of the modality.
- The arterial pulse waveform analysis (APWA)-derived measures may be inaccurate and trend toward inferiority in certain subgroups. Unfortunately, these groups define patients where resuscitative guidance is critical. These include higher acuity abdominal and emergency surgery patients, severe sepsis, burn resuscitations, pressure support ventilation, or any condition where vascular tone is altered due to disease or vasopressors. APWA is associated with narrow applicability parameters in an acutely unstable mixed population of critically ill. In addition, uncalibrated devices appear to be more prone to error. Further, there is an unknown risk of bias in the many investigations that utilize the same APWA modality to administer the index test as well as to define the reference standard.

Qualifying Statements

Qualifying Statements

- The Eastern Association for the Surgery of Trauma (EAST) is a multi-disciplinary professional society committed to improving the care of injured patients. The Guideline Section of EAST develops and disseminates evidence-based information to increase the scientific knowledge needed to enhance patient and clinical decision-making, improve health care quality, and promote efficiency in the organization of public and private systems of health care delivery. Unless specifically stated otherwise, the opinions expressed and statements made in this publication reflect the authors' personal observations and do not imply endorsement by nor official policy of EAST.
- "Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."* These guidelines are not fixed protocols that must be followed, but are intended for health care professionals and providers to consider. While they identify and describe generally recommended courses of intervention, they are not presented as a substitute for the advice of a physician or other knowledgeable health care professional or provider. Individual patients may require different treatments from those specified in a given guideline. Guidelines are not entirely inclusive or exclusive of all methods of reasonable care that can obtain/produce the same results. While guidelines can be written that take into account variations in clinical settings, resources, or common patient characteristics, they cannot address the unique needs of each patient nor the combination of resources available to a particular community or health care professional or provider. Deviations from clinical practice guidelines may be justified by individual circumstances. Thus, guidelines must be applied based on individual patient needs using professional judgment.
- A potential weakness of the review is that the acknowledged variability in study types and populations and broad definitions of outcomes make it difficult to address specific knowledge gaps. However, as evidenced by the multitude of focused ultrasound and arterial pulse waveform analysis (APWA)-based protocols and their use in undifferentiated shock, the review team elected to include the multiple potential roles for these modalities as applied to a broad definition of shock across many populations to identify favorable clinical applications.

*Institute of Medicine. Clinical practice guidelines: directions for a new program. MJ Field and KN Lohr (eds) Washington, DC: National Academy Press. 1990: pg 39.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Plurad DS, Chiu W, Raja AS, Galvagno SM, Khan U, Kim DY, Tisherman SA, Ward J, Hamill ME, Bennett V, Williams B, Robinson B. Monitoring modalities and assessment of fluid status: A practice management guideline from the Eastern Association for the Surgery of Trauma. J Trauma Acute Care Surg. 2018 Jan;84(1):37-49. [74 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2018 Jan

Guideline Developer(s)

Eastern Association for the Surgery of Trauma - Professional Association

Source(s) of Funding

Eastern Association for the Surgery of Trauma (EAST)

Guideline Committee

Subsection of the Surgical Critical Care Task Force of the Practice Management Guideline Committee of Eastern Association for the Surgery of Trauma (EAST)

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Financial Disclosures/Conflicts of Interest

The authors declare no conflicts of interest.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the Journal of Trauma and Acute Care Surgery Web site .

Availability of Companion Documents

The following is available:

Kerwin AJ, Haut ER, Burns JB, Como JJ, Haider A, Stassen N, Dahm P, Eastern Association for the Surgery of Trauma Practice Management Guidelines Ad Hoc Committee. The Eastern Association of the Surgery of Trauma approach to practice management guideline development using Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology. J Trauma Acute Care Surg. 2012 Nov;73(5 Suppl 4):S283-7. Available from the Eastern Association for the Surgery of Trauma (EAST) Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on February 6, 2018. The information was verified by the guideline developer on March 26, 2018.

This NEATS assessment was completed by ECRI Institute on February 8, 2018. The information was verified by the guideline developer on March 26, 2018.

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